MOWA®CE

Mobile Wound Analyzer

User Manual

Index

1 **Introduction** 3
1.1 Trademark information 3
1.2 Safety and privacy 3
1.3 Conformity Assessment 3
2 **Starting** 4
2.1 Using this manual 4
2.2 System requirements 4
2.3 Product Information 4
2.4 Proper use and limitations 4
2.5 Language 5
2.6 Starting the program 5
3 **Analysis Process** 6
3.1 Getting an image 6
3.1.1 Getting an image (Android) 6
3.1.2 Getting an image (IOS) 6
3.2 Creating the Mask Area 7
3.3 Image analysis 8
3.4 Setting wound parameters 9
3.5 Calculus of the lesion area 10
3.6 Results and therapeutic treatment 11
3.7 Analysis final report 12
4 **Additional Functions** 13
4.1 Sharing JPG analysis file 13
4.1.1 Sharing MOWA JPG file (Android) 13
4.1.2 Sharing MOWA JPG file (iPhone) 13
4.2 Sending PDF report document 13
4.3 Drawing the mask 14
4.3.1 Drawing tools 14
4.3.1.1 Pen and Finger 14
4.3.1.2 Size of stroke 14
4.3.1.3 Eraser 14
4.3.1.4 New 14

1 Introduction

1.1 Trademark information

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1.2 Safety and privacy

Read carefully the following instructions. Improper use can give wrong analysis results. Only health professionals should use MOWA.
The program doesn't use or need any personal (private) data to be functional.

1.3 Conformity Assessment

MOWA is a Medical Device of Class I, Medical Devices Directive 93/42/EEC, and amended by 2007/47/CE. The medical device is in conformity with the essential requirements of Annex I of the EEC directive. The conformity assessment procedure was performed according to Annex VII (class I) of the EEC directive.
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2 Starting

2.1 Using this manual

This manual targets all users that want to learn to use Mowa. Its organization is based on the specific activities necessary to get the objectives through detailed instructions. For its proper use remember the following conventions.

	Warnings, previous conditions or instructions that must be followed rigorously.
	More information or hints.

2.2 System requirements

MOWA (Mobile Wound Analyzer) is a software application for smart-phones and Tablets running Android OS 2.1 or higher and iPhone/iPad devices running iOS 4.2 or higher. The device running Mowa must have a rear photo camera with a minimum resolution of 1.3 megapixels and touch screen capability.

2.3 Product Information

The aim of the software is to provide the health professional with a tool for the study of pressure sores and for training. The software makes possible to differentiate types of tissues found in pressure sores. The analysis can be made on photos taken with the on board camera or uploaded pictures from other sources. It identifies three types of tissues in the bed of the lesion: Necrotic, fibrin and granulation. Calculates the area of the lesion and indicates the treatment following the directions of EPUAP LG - NPUAP.

2.4 Proper use and limitations

1. This software analyzes only the pressure ulcer bed and not the surrounding skin.
2. This software analyze pressure ulcers from Class II onwards (NPUAP-EPUAP classification)
3. This software must be used for educational, informational and for objective comparisons.
4. This software contains information about the treatment of pressure ulcers as, at the time of publication, are appropriate to the LG-NPUAP EPUAP. Is our commitment to provide continuous updates of these directives.
1. This software is able to compute the area of Pressure Ulcers from 2 mm to 30 cm in width.
2. The calculation of the Pressure Ulcer area is conditioned by the precision with which the operator measures the width of the lesion and draws the mask.
3. The deepness influence the treatment not the calculated area.

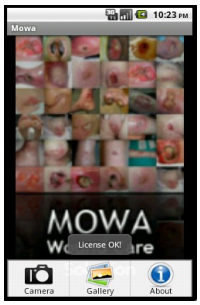
4. Identification of tissues in the wound bed (necrotic, fibrin, granulation) is influenced by the quality of the photo.

2.5 Language

MOWA supports 4 languages: English, Italian, French and Spanish.

2.6 Starting the program

To launch the program tap the Mowa icon on the smart-phone and the main screen will be shown.



Android

iPhone

3 Analysis Process

3.1 Getting an image

	Warning: improper light conditions can influence the quality of the analysis. The flash reflections also can disturb the color separation.
	It's advised to operate in adequate ambient light conditions and to reduce the use of the flash.

3.1.1 Getting an image (Android)

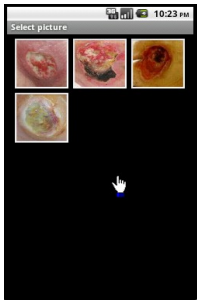


Image acquisition can be done directly using the camera on your smart-phone or tablet, or importing one from the picture gallery already on the device. You need to tap on the Camera or Gallery button accordingly. Also it is possible to load a jpg file into Mowa from an other application selecting Mowa as the viewer. Mowa registers itself as a system image viewer for jpg files. You can go to the home page of Mowa from any menu in the program tapping on the home button. Once the image has been acquired Mowa displays the “Image name” dialog if you want to modify it, press OK when done.

3.1.2 Getting an image (IOS)

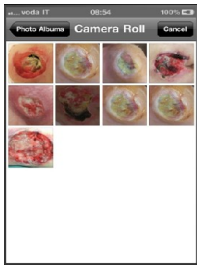
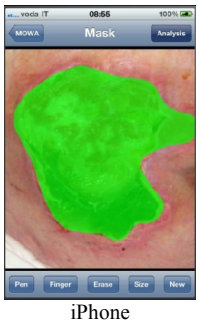


Image acquisition can be done directly using the camera on your smart-phone or tablet, or importing one from the picture gallery already on the device. You need to tap on the Camera or Gallery button accordingly. You cannot give a name to it, iPhone Media Gallery uses an automatic name assignment.

3.2 Creating the Mask Area

	Warning: the accuracy of the mask design is paramount to the correctness of the analysis.
	Optimize the mask design using the dimension tool . Choose the pen or the finger tool.

Android

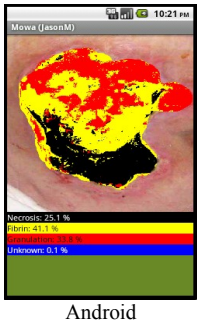


iPhone

The mask area page is visualized right after a new image acquisition. The Mask Area is essential: is the only way in which MOWA can recognize which specific parts of the image you want to be analyzed. To draw the Mask, MOWA does not use vectors or geometrical shapes, you simply draw it freehand (figure 2). The total amount of pixels set in the Mask is used in the calculus of the wound area. The Mask Page can be accessed from the Start Menu pushing the Mask Icon.

3.3 Image analysis

	The analysis will be meaningless if you use images that not correspond to pressure sores.
	Verify the percent of unrecognized tissues. Consider to take a new picture or modify the mask if it is more than 10%.

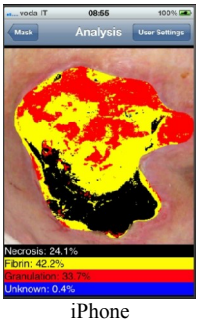


Android

After drawing the mask, the special algorithm created specifically for this application, calculates and identifies the tissues present in the wound image by three colors:

5. black
6. yellow
7. red

the quantities, expressed in percent of recognized tissues in the whole analyzed area, are classified as:



iPhone

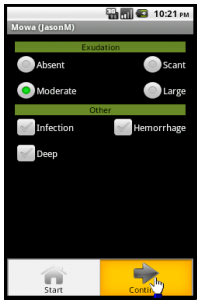
1. necrotic tissue (black)
2. fibrin tissue (yellow)
3. granulation tissue (red)

The blue color percentage indicates the amount of unrecognized tissue area of the whole mask. This could be caused by corruption of the image, light effects, flash reflections, etc.

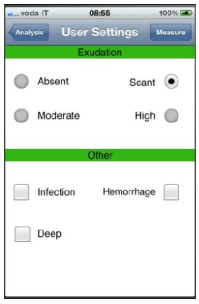
Tissue classification from color images could be different between photo and photo or among different devices. The causes could be various. Among the elements that could corrupt image color analysis are: illumination, flash reflection, resolution, jpg codec and more. For example, differences have been observed between the jpg codec in some Smart-phones and Tablet PCs. This can produce a difference between tissues percentage in a range of 0,1%-5%. Our purpose, now and in the future, is to reduce the differences improving the analysis algorithm or using a custom embedded codec. Normally these percentage differences don't invalidate the therapeutic prescription.

3.4 Setting wound parameters

	Warning: the health professional sets this parameters making a direct observation of the sore.
	Make a careful evaluation of the lesion.



Android



iPhone

Necessary condition for the software to show the appropriate therapeutic treatment for analyzed tissues is to indicate:

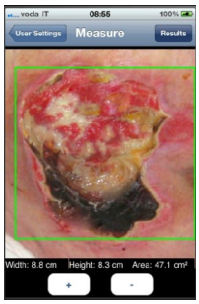
1. Exudate amount
2. Presence of Infection
3. Presence of Hemorrhage
4. If the lesion is deep

These parameters must be set by the professional operator

3.5 Calculus of the lesion area

	Warning: the calculus of the area will be exact if the user did an accurate measure of the width of the lesion.
	Use the surrounding rectangle as a reference for to measure the width of the wound. Use a tape measure or a ruler.

Android

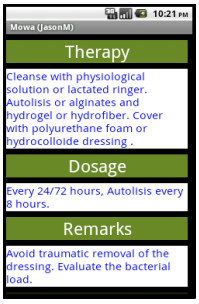


iPhone

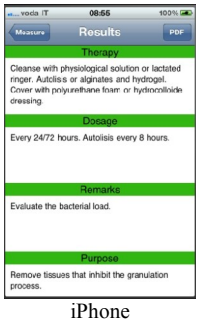
After work area was defined (MASK AREA) and the lesion parameters have been set, the operator has to measure the real size of the lesion with a tape measure (or a ruler) directly on the patient. With the plus and minus buttons the operator sets the size of the surrounding rectangle accordingly. At this instance MOWA is able to calculate the real area of the lesion expressed in cm^2. This calculated area is actually the area of the mask scaled properly, not that of the surrounding rectangle. The area can be computed in lesions from 2 mm up to 300 mm (30 cm) in the largest dimension (width or height).

3.6 Results and therapeutic treatment

	Warning: The suggested treatment is not to be considered as a prescription.
	The health professional decides the therapeutic treatment based on his own experience.


10:21 PM
Mowa (JasonM)
Therapy
Cleanse with physiological solution or lactated ringer. Autolisis or alginates and hydrogel or hydrofiber. Cover with polyurethane foam or hydrocolloide dressing .
Dosage
Every 24/72 hours, Autolisis every 8 hours.
Remarks
Avoid traumatic removal of the dressing. Evaluate the bacterial load.

Android

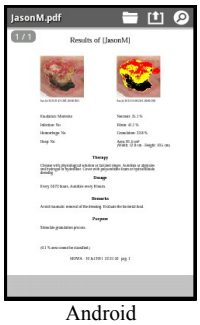


iPhone

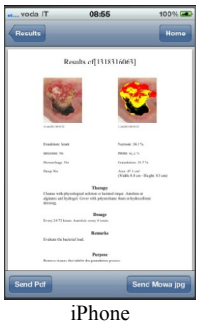
The last stage of the process consists in the therapeutic treatment. Suggested on the base of the therapeutic effects that are carried out by the active principles of the dressing, drugs, etc.

3.7 Analysis final report

	Warning: the report is not a medical document.
	The final report may be used as an example and/or archived as a reference for future comparative analysis.



Android



iPhone

The final report will be saved or sent as a PDF document insuring the report portability.

4 Additional Functions

4.1 Sharing JPG analysis file

Mowa is able to send and receive files in JPG format by e-mail. The sent image contains also the mask, measures and settings. This feature permits to receive, view, and repeat the whole process in a different device (Mowa must be installed on both devices).

	Warning: The JPG file contains all the information of the original image analysis.
	Avoid to edit or manipulate the Mowa JPG generated file with any image editor.

4.1.1 Sharing MOWA JPG file (Android)

Sharing a MOWA JPG file with other smart-phone o tablet is very simple.

The sender side

1. Completes the analysis of the sore.
2. Touches Send button in MOWA menu.
3. Selects Mowa jpg as the type of file to send.
4. Chooses the sending method (mail, bluetooth ...) .

The receiver side

1. Receives and save the jpg file.
2. Opens jpg file selecting MOWA as the viewer.
3. Uses MOWA for viewing the wound analysis.

4.1.2 Sharing MOWA JPG file (iPhone)

The iPhone version of MOWA can only send the jpg file for sharing but it cannot receive the MOWA jpg with the included parameters. Obviously you can always save the image attached in the e-mail and reprocess it with MOWA drawing a new mask and setting all the parameters.

4.2 Sending PDF report document

The final report (PDF) can be sent at the end of the analyzing process as an attached document by mail. Use the Send button in the last screen of MOWA and complete the mail data, the pdf file is attached automatically.

4.3 Drawing the mask

For improve the drawing of the mask there are some extra tools:

4.3.1 Drawing tools

4.3.1.1 Pen and Finger

These two modes are aimed to ease the drawing in small screens or with large fingers. The finger tool draws immediately over the point the finger touches the screen avoiding to cover the drawing path. The pen tool (use a compatible pen with your device) draws exactly at the point the pen touches the screen.

4.3.1.2 Size of stroke

This tool permits to size the diameter of the drawing pen or finger. You can use a small diameter for the details on the borders and a bigger one to fill the inner area.

4.3.1.3 Eraser

Use this tool to erase any unwanted part of the mask you drew before.

4.3.1.4 New

With this tool you erase the whole mask and you restart with an empty mask canvas.

(Note: the mask is only saved when you pass from the Measure Screen to the Results Screen. Any change you make without passing from these stages will not be saved for future analysis and are only applied for the current analysis.)